

SCOTTSDALE
SKIN & CANCER
CENTER, LTD.

10900 N. Scottsdale Road Suite 502 Scottsdale, Arizona 85254

JOSEPH M. SCHERZER, M.D.

Diplomate of the American Board of Dermatology
Diplomate of the American Board of Dermatopathology

June 5, 1998

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Food and Drug Administration
Dockets Management Branch (HCFA-305)
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

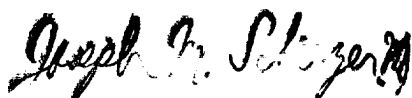
Re: Section 503(A), RFA Modernization Act of 1997
Docket No. 98N-0182

To Whom It May Concern:

Just a correction to the enclosed previously sent letter. The name of the gel base supplied by C&M Pharmacal is "Gel Base R."

Thank you.

Sincerely,



Joseph M. Scherzer, M.D.

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98N-0182

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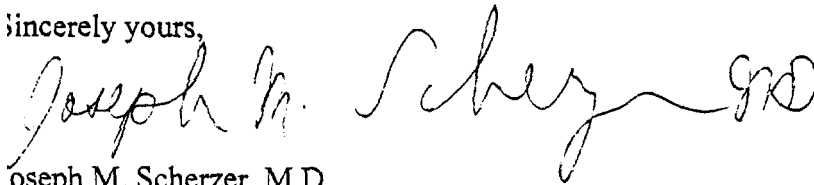
Johnson makes no claim whatsoever that **Renova** is safe for acne, while the other brand name of .05% **retinoic** acid, **Retin A**, is marketed directly for acne.)

As far as the gel base is concerned, it also offers advantages. Retin A uses specially denatured **ethyl** alcohol, while C&M uses isopropyl alcohol. Retin A (**Ortho**) uses **hydroxypropylcellulose** as a **gellant** while C&M uses **Carbomer** 940. I prefer C&M's agents; the final product is **smoother**, and has had great patient acceptance.

I am using these cream and gel bases for the sole purpose of compounding these **tretinoin** **formulations** I have just described.

There are many examples in dermatology of the importance of specific bases, which can make **all** the difference in the **world** to patients. The selection of such should be left to the individual practitioner. For example, if I prescribe **Aristocort A** cream for **my** patients with a dry skin **condition** called eczema (**atopic** dermatitis), I will help them by use of its moisturizing base. If I **permit** a generic substitution (which many **formularies** are now demanding), my patients can well wind up with the same active ingredient formulated in a drying, desiccating vehicle, which can **dry** out their skin and make their eczema worse instead of better. we need to be able to do what we are trained to do, for the best interests of the patients and the profession as a whole.

Sincerely yours,

A handwritten signature in cursive script, reading "Joseph M. Scherzer" followed by a stylized "MD". The signature is written in black ink on a white background.

Joseph M. Scherzer, M.D.

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Food and Drug Administration
Cosmetics Management Branch (HIF A-305)
1420 Parklawn Dr., Room 1-23
Rockville, Maryland 20857
June 3, 1998

Re: Section 503(A), FDA Modernization Act of 1997
Docket No. 98N-0182

To Whom It May Concern:

Following just learned of this act, and of an imminent deadline concerning same, I wish to nominate two vehicles I am using to compound several forms of **retinoic acid** for my patients.

I am compounding three different strengths of a **retinoic acid** cream (0.025%, 0.05%, and 0.1 %) and two different strengths of a **retinoic acid** gel, using Cream Base R from C & M Pharmacal for the cream, and a gel base for the gels. these are used topically only, for acne, and comedones.

Pursuant to section 503(A), (a)(2) (A), I am a licensed physician in active private practice in Arizona, compounding these products in limited quantities before the receipt of a valid prescription order for individual patients, and (B) also based on my history as such a licensed physician having received many prescription requests for all of these products over many years for my patients, who are the only individuals for whom I prescribe such products (B)(ii)(I).

Regarding 503(A)(b)(2) [Definition], I am using drug products which represent a change made for my aforementioned patients which produces for those patients a significant difference, as determined by myself, between the compounded drug and commercially available drug product. Here is the information you require about the bulk drug substances I am using:

I am using (as a main ingredient) **retinoic acid (tretinoin)**, USP chemical grade, supplied to me in crystalline form. As far as bibliographical information concerning its safety and efficacy, I would refer you to Ortho's Retin A NDA

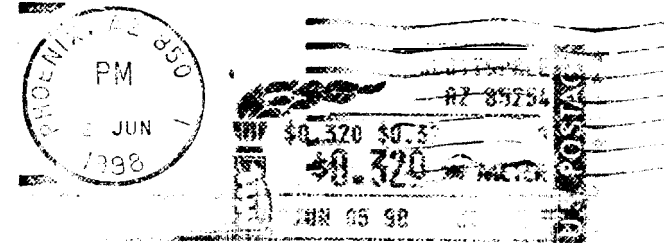
I formulate 0.025%, 0.05% and 0.1% cream forms of this, and 0.01% and 0.025% gel forms - all topical preparations.

The cream base R supplied by C&M Pharmacal, unlike Retin A, has no isopropyl myristate, avoiding a potential irritant. Unlike Renova, the has. has no Mineral oil, thus avoiding potential comedogenicity. Also, unlike Renova, I can provide two other strengths of retinoic acid in a cream base, and offer better therapeutic effects for my patient population. Many of my patients who request a **Renova-like** product are younger, rather than older patients, and either prone to acne or currently being treated for it. **Renova** would not be appropriate here. (Johnson and

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